**Replacement Specification Pages** 

APPENDIX B



# **BACKGROUND**

This invention relates to a safety syringe, which has a cylinder, a syringe needle, a needle holder associated to the cylinder and adapted to hold the syringe needle, and a plunger associated to the cylinder, wherein the plunger comprises a piston and serves to inject a filling of the cylinder via the syringe needle.

#### **SUMMARY**

The invention provides a syringe having the features of claim 1. For particular high safety, the features of claim 2 are suggested. Advantages with respect to the safety are also obtained for the features of claim 3 or - alternatively -of claim 4. Substantial advantages are further obtained from the features of at least one of claims 5 to 8, which concern the coupling of the plunger with the needle holder and the fixation of the needle holder to the cylinder in the region of a front hole of the cylinder. Other possible features of a syringe according to the invention, which give further advantages, can be found in the following specification or/and in the figures.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

A first embodiment, which serves to illustrate a syringe according to a first aspect of the invention, is shown in figures 1 to 11. The figures show:

- Fig. 1; Cross-sectional view of the parts.
- Fig. 2; Squint view of the parts.

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Fig.	3:	Lateral	view	٥f	the	cylinder.
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- Fig. 4; Lateral view of the syringe needle inserter.
- Fig. 5; Front view of the syringe needle inserter.
- Fig. 6; A-A line cross-sectional view of the Fig. 5.
- Fig. 7; B-B line cross-sectional view of the Fig. 5.
  - Fig. 8; Front view of the plunger.

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- Fig. 9; Cross-sectional view of this device when injection is completed.
- Fig. 10; Cross-sectional view of the device when plunger meets 2 the syringe needle fixer upon completion of injection.
- Fig. 11; Cross-sectional view of this device which shows the breaking of the plunger after pulling the plunger back into the cylinder in order to keep the syringe needle and the syringe needle fixer inside the cylinder.

A second embodiment, which serves to illustrate a syringe according to a second aspect of the invention, is shown in figures 12 to 25. The figures show:

- Figure 12; A partial longitudinal corss-section of the syringe.
  - Figure 13; An isometric exploded view of a needle inserting device.
  - Figure 14; A view of the plunger.
  - Figure 15; A longitudinal cross-section of the syringe without needle.
- Figure 16; A longitudinal cross-section of the syringe without needle that the plunger is
  assembled with the needle needle inserting device.
  - Figure 17; A partial cross-section shows breaking off the plunger after injection.
  - Figure 18; A longitudinal cross-section of the syringe covered with a part. separated from the

#### plunger

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Figure 19; A longitudinal view of the needle inserting device.

Figure 20; A A-A line cross-section in Fig. 12.

Figure 21; A another A-A line cross-section in Fig. 12.

Figure 22; A B-B line cross-section in Fig. 12.

Figure 23; A C-C line cross-section in Fig. 19.

Figure 24; A E-E line cross-section in Fig. 19.

Figure 25; A F-F line cross-section in Fig. 19.

The first embodiment and/or the second embodiment serve to illustrate further aspects of the invention.

## **DETAILED DESCRIPTION**

In the following, a safety syringe according to the first aspect and further aspects of the invention is explained.

This device is for a safety syringe preventing a third person from getting damaged by the used syringe needles. It is designed to keep the syringe needle in custody of syringe cylinder once used so that a third person may not be pricked by the used needles. The plunger shall then be broken after use in order to prevent from being used again.

In order to prevent repeated use of syringe needles by far, it is the current phenomenon that disposable syringes are predominantly being used. Such conventional disposable syringes have been technically designed to prevent to be reused.

The conventional disposable syringes are, however, after being used, usually or

frequently being disposed or not properly dealt with the needles and thus a third person may be easily pricked. Such problems of giving damages to a third party have not been solved.

Because the syringe needles always have blood stain, in case medical workers including doctors and nurses as well as a third party get pricked by an used syringe needles they are very much concerned of being infected by the disease of the patients (AIDS, hepatitis, etc.) and such cases have been reported.

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This device is a safety syringe system which prevents disease from being infected to a third party via used syringe needles by keeping it inside the syringe cylinder.

According to this device, the used needle does not need to be taken off from the syringe after use, but, instead, it is pulled into the cylinder to be fixed and kept in custody inside cylinder. And by doing this, infections of disease to a third party by getting pricked can be prevented.

My previous patent application of this nature regarding safety syringe system have been published on the Utility Model Announcement Korea Utility Model No.91-4532 and Open Utility Model Public News Korea Utility Model No.96-13409.

This device is to introduce more advanced safety syringe system which is simpler in structure and more reliable in affect compared with the above-said previous patent.

Technical Target that this device pursue to accomplish.

My previous safety syringe system published on the Utility Model Announcement

No.91-4532 and Open Utility Model Public News No.96-13409 was to have the needleset fixed
to the plunger so that the syringe needle can be kept inside cylinder when the plunger is pulled back.

This disposable syringe that I have patented as above had some defects requiring a host of parts and extreme preciseness whereby creating difficulties in manufacturing. This device has been developed instead. It is simpler in structure, easier in manufacturing, has eliminated the possibility of mis-use and requires less number of parts.

In the following it is referred to Fig. 1 to 11.

Structure and action of the device.

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It has cylinder for injection. Inside the cylinder are piston and plunger. In a syringe Which the dead-end of the cylinder has a syringe needle usually affixed, cylinder (11), syringe needle (21), syringe needle inserter (31) and plunger (41) are the parts in structure. At the end of inserting hole of the cylinder are a host of projection (13) and incised grooves arranged alternately. On the inner face of the cylinder are stopping sill (15) and obstacle (hooking?) sill at the rear end. At the center of the syringe needle inserter (31) is the syringe needle fixer (32). On the outer face (33) of barrel shaped syringe needle fixer (32) are number of "-i' shaped grooves (34) for projections (13) to enter. Packing (35) is placed in its rear. Inside of the rear-end are projections prominence (36) on the top and bottom. Inside both of the up/down projections aforesaid is formed the obstacle (hooking) inside ring stopper (37). On the tip of the plunger (41) where piston (42) is inserted are top/bottom connecting device (43) which have hooking sills (43'). On both sides of the central projection (44) are erected projections (44'). At the end of the plunger (41) where piston (42) is inserted forms a space (47). Pressing button (48) at the rear part of the plunger (41) has a inserting groove (48'). The inserting groove (48') is for the cap (49) to be inserted to cover the inserting hole (12) of the cylinder tip.

In order for the plunger (41) to be easily broken, in the fore part of the plunger (41) are many "V" shaped grooves or holes and at the rear part of the piston (42) of plunger (41) is formed a stopping ring sill (50).

This device with such structure will act as follows:

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Cylinder (11) and the syringe needle inserter (31) are combined together by thrusting the needle inserter (31) from the rear end of the cylinder (11) to the inside of the cylinder until the projections (13) on the inner face of the cylinder (11) insert hole (12) meet and set in the "¬" shaped grooves formed on the outer face of the barrel shaped needle inserter (31).

Then the piston (42) inserted plunger (41) is pushed into the rear side of the cylinder (11). Right before the use of the syringe, syringe needle (21) is fixed in the syringe needle inserter (31) as usual. Injection is sucked into the cylinder (11) by pulling the plunger backward. Injection is done to the patient by pushing the plunger (41).

At the time when the syringe needle inserter (31) is fixed to the cylinder (11) from the rear toward inner side, it has to be pushed until the projections (13) of inserting hole (12) of the cylinder set in toward the circumference direction of the "¬" shaped grooves of the syringe needle inserter (31). At this time, the incised grooves between projections (13) will help syringe needle inserter (31) entering into the cylinder (11) by making the cylinder (11) tip bursted open so that the needle inserter (31) can be easily set in.

The stopping sill (15) of the inner face of the cylinder (11) joints the rear tip of the syringe needle inserter (31). The packing (35) inserted in the syringe needle inserter (31) will closely adhere to the inner face of the cylinder (11).

When the syringe inserter (31) is inserted by force into the inserting hole (12) of the

cylinder (11) tip in order to fix the syringe needle inserter (31) onto the cylinder's (11) tip, the projections (13) of the inner face of the cylinder (11) will be hooked on any of the "¬" shaped grooves (34) of the outer face of the syringe needle inserter (31), that is, on the groove of any location in circumference direction, but as the syringe needle inserter (31) turns accordingly when we turn and fix the syringe needle (21) in the syringe needle inserter (31), the projections (13) erected in the inserting hole (12) of the cylinder (11) will become to locate at the last of the "¬" shaped grooves as soon as the syringe needle is fixed in.

Moreover, as the meeting places of the "¬" shaped grooves are not flat but are "U" or "^" shaped, the projections (13) of cylinder (11) cannot be located on the border between the "¬" shapes.

Like this, the syringe needle inserter (31) and syringe needle are fixed at the cylinder (11) tip, and by thrusting the plunger (41) into the cylinder (11), syringe assembly is completed. The syringe sucks the injection into the cylinder (11) when the plunger (41) is pulled back. After plucking the needle (21) from the patient (Ref. Fig. 9) upon completion of injection, if we apply force to push the plunger (41) forward (Ref. Fig. 10), piston (42) is being pressed so as for its volume to become smaller by the space (47) formed inside of the piston (42), and at the same time, the respective hooking sills (43') of upper and lower connecting device (43) formed up and down the plunger (41) is inserted in the obstacle ring sill (37) of the inner face of the rear part syringe needle inserter (31), plunger (41) tip and the syringe needle inserter (31) rear part will be combined together when the plunger (41) is turned, the projection (44') erected both sides of the central projection (44) of the plunger tip will joint the up/down projections (36) of the rear inner face of the syringe needle inserter

(31), and the truning plunge (41) will turn the syringe needle inserter (31).

The syringe needle inserter (31) which is truned by the plunger (41) is again turning the "¬" shaped grooves (34), then the projections (13) of the cylinder (11) will turn the straight line of the "¬" shaped grooves (34). When the plunger is drawn back, the projections (13) will be pushed forward along the straight lines of "¬" shaped grooves, and at the same time, the needle inserter (31) as well as the syringe needle (21) which is inserted thereto will be pushed back to inside of cylinder (11).

Backtracking plunger (41) will retreat until the plunger ring sill (40) reaches the hocking sill (16), then plunger (41) is to be broken. Then all the operation comes to an end by trans-inserting the cap (49) which is inserted in the pressing hole (48) into the inserting hole (12) in front of the cylinder (11).

In the cap's (49) inserting hold is prepared a ring(circular) sill and because the ring sill of the cap (49) insert hole is to meet the projection (13) of the insert hole (12) of cylinder (11), the cap inserted in the insert hole (12) would not easily come out.

Effect of this device.

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This device is designed to withhold the used syringe needle inside the cylinder, the main body of syringe, and whereby to prevent the possible damages which may happen to medical workers including doctors and nurses as well as a third party from being pricked by the used syringe needles.

The syringe needs to be dealt with utmost care regardless before of after use, due to the sharp-pointed needles. A special attention is required to be paid to the used ones because of the blood stain. Especially, because hepatitis and AIDS are infectious to a third party via blood

stain, the syringes used for patients of such disease must be handled with special attention.

However, as described in this device, if we insert the used syringe needle into the cylinder and then break the plunger, the syringe needle will be located inside the cylinder. If we cover the cylinder with the cap prepared in the rear of the plunger, there is no possibility at all for the syringe needle inside the cylinder to be exposed out of the cylinder and can be kept safely in custody until further process. If we use this device, we cannot re-use the used syringes. Therefore, it is very useful device as it can prevent disease caused by the used syringe needles from being infectious to a third person.

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This device is designed to keep the used syringe needle inside the cylinder prohibiting re-use of the used syringe needles in order to prevent possible damages for medical workers including doctors and nurses and a third party alike to be taken from being pricked by the used syringe needles. The syringe needle which is fixed in the syringe needle fixer is set at the tip of cylinder with the help of the syringe needle inserter.

Inserting part is composed at the projection of the tip of the plunger which is to be put in the cylinder. At the rear end of the syringe needle fixer is formed the assembling part. The projection of the plunger joints the syringe needle fixer. When plunger is drawn back, syringe needle fixer with its needle fixed in will also be drawn back and kept inside the cylinder. Thus, damages by the used syringe needle can be prevented. This device is of the safety syringe which can prevent in infectious diseases such as hepatitis and AIDS.

Some important aspects of the safety syringe according to the first embodiment are as follows:

It has cylinder to suck in injection. Piston and plunger are in the cylinder while the ordinary syringe has the syringe needle affixed to the syringe, this device has the cylinder (11),

syringe needle (21), syringe needle inserter (31) and plunger respectively as parts of its structure. At the insert hole (16) of the above said cylinder (11) tip are a host of projections (13) and incised grooves (14) arranged alternatively one after another. Cylinder's (11) inner face has stopping sill and hooking sill in the rear. At the center of the syringe needle inserter is a syringe needle fixer to fix syringe needle. Outer barrel shaped outer face of the syringe needle fixer has a number of "¬" shaped grooves for projections (13) formed on the inner face of the insert hole (12) to set in. Packing (35) is set in the rear. On the upper and lower part of the inner face of the rear part are projections (36). Inside the upper and lower projections (16) is hooking ring sill (37). At the plunger (41) tip where piston is inserted in are top and bottom joints connecting device which has hooking sill (43'). On both sides of the central projection (44) inside the top/bottom joint connecting device. Space (47) is formed at the plunger (41) tip where piston is inserted in. At the pressing/pushing button (48) of the rear end of the plunger (41) has the insert groove (48'). In the insert groove (48'), a cap (49) is supposed to be inserted to cover insert hole (12) of the cylinder tip.

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In the following, a safety syringe according to the second aspect and further aspects of the invention is explained.

This device relates to a safety syringe so as to prevent a pricking of other person by means of withdrawing a needle in the inside of a barrel keeping in it after injection and the reuse of a syringe by means of breaking off a plunger.

The prior single use syringe which a technical method is applied to in order to prevent the reuse of a used syringe was usual.

But there was the possibility of pricking by a used needle because the prior single use

syringe is left or thrown away, holding the needle on the syringe. Thus the problem that other person might be damaged with the used needle couldn't be solved by the single use syringe.

That is, some blood is left on the needle after injection. In that case, if doctor, nurse, medical employee or other person was pricked by the used needle, they might be infected with the disease of the patient (such as AIDS, hepatitis and the like) by it. The examples are actually reported.

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This device relates to the safety syringe so as to prevent transmitting the infectious diseases through the used needle, withdrawing the used needle into the inside of a barrel and keeping it in a barrel without removal of the needle, after injection.

As a prior patent documents on a safety syringe, there is Utility Model Announcement #91-4532 and Open Utility Model Announcement #96-1 3409 which were applied by this applicant and were announced. And also this applicant applied for utility model of a safety single use syringe in Utility Model Application #7783 in 1999.

This device has more simple structure and exact function than prior syringes which was applied by this applicant before.

The safety syringes that the needle set is fixed to the plunger, withrawn into the inside of a barrel and kept in it after injection are shown in Utility Model Announcement #91-4532, Open Utility Model #96-13409 and Utility Model Application #7783, which were applied by this applicant and announced.

The prior single use syringes which were applied for utility model by this applicant had a problem in manufacturing because those need a great number of parts and high precision as this device is newly developed in order to remove the demerits, it needs few number of parts,

the structure is simple, manufacturing is easy and the possibility of the incorrect operation gets removed.

In the following it is referred to Fig. 12 to 25.

[Structure of device]

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Same as a general syringe has a barrel which medication is sucked into, a piston and a plunger in the inside of a barrel.

This safety single use syringe is composed of a barrel (11), a needle (21), a plunger (41) and a needle inserting device (31) to which a needle (21) is attached. A number of projections (13) are in the inside of the front end of an inserting hole (12) of the above barrel (11), an annular stop prominence (15) is on the inner circumferential surface of a barrel (11), an annular restraining prominence (16) is at the rear end of a barrel, a needle locking device (32) to attach a needle (21) is at the center of a needle inserting device (31), a number of "¬" shaped female grooves (34) having the wide entrances in order to be assembled with a projection (13) located at an inner surface of an inserting hole (12) of the above cylindrical barrel (11) are on the outer cylindrical surface (33) of a needle locking device (32), a 0-ring (35) is inserted at the rear of the grooves, a number of female grooves (37) are in the inside of a needle inserting device (36), a male extensions (43) having each restraining prominence (43') are at the front end of a plunger (41) to be assembled with a piston (42), an empty space (47) is at the front end of a plunger (41) to be assembled with a piston (42), a cutting notch (45) is at the front part of a plunger (41) in order to be easily broken off, an annular stop prominence (50) is at the rear part of a plunger (41), rear stop projections (51) are at the longitudinal center of a plunger, an empty space (53) is longitudinally in the central inside of a plunger (41)

between rear stop projections (51) and cutting notch.

The device having this structure operates as follows:

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A needle inserting device (31) is inserted into a barrel from the back end of a barrel (11) and pushed towards the front end until a number of projections (18) in the inside of a inserting hole (12) of a barrel (11) reaches the end of "¬" shaped groove (34) having a wide entrance on the cylindrical outer surface (33) of a needle inserting device (31), and assembled with a barrel (11).

And then a plunger (41) assembled with a piston (42) is inserted into a barrel from the back end of a barrel (11) and a needle (21) is put into a needle inserting device (31) just before using a syringe. A plunger (41) is pulled back and medication is sucked into the inside of a barrel(11) as usual. Medication is injected into a patient's body, a plunger (41) being pushed.

When a needle inserting device (31) is inserted into a barrel (11) from the back end of a barrel (11) and fixed to a barrel, a needle inserting device (31) is pushed into a barrel until a number of projections (13) in the inside of an inserting hole (12) of a barrel (11) reaches the end of the "¬" shaped groove (34) having the wide entrance on the outer surface of needle inserting device (31). In this case an annular stop prominence (15) on the inner surface of a barrel (11) meets the back end of a needle inserting device (31) and an 0-ring (35) inserted into a needle inserting device (31) clings to the inner cylindrical surface of a barrel (11) so that sealing is completely kept.

When a needle inserting device (31) is pushed into an inserting hole (12) at the front end of a barrel (11) and locked, the projections (13) on the inner circumferential surface of a barrel (11) is positioned at the back end (the entrance of the groove) of the "¬" shaped female

groove (34) having the wide entrance on the outer circumferential surface of a needle inserting device (31). But when a needle (21) is put into a needle inserting device (31) and locked, the male projections (13) in the inside of an inserting hole (12) of a barrel (11) is positioned at the end of "¬" shaped female groove (34) because both the needle (21) and the needle inserting device 31 is rotated together.

Thus, a needle inserting device (31) and a needle (21) is at the front end of a barrel (11) and a plunger (41) is inserted into a barrel (11) so that the assembly of a syringe is finished. The plunger (41) is pulled back, the medication is sucked into a barrel and it is injected to a patient's body, after medication is injected to a body and a needle (21) is withdrawn from it, as additional force is applied to a plunger (41) (Figure 5), a piston (42) which has an empty space (47) inside is pressed and squeezed. At the same time each restraining stop projections (43') of a locking device (43) is locked in the inside of a female groove (37) located at the outside of a central hole of a needle inserting device (31) so that the front end of a plunger (41) is connected with the back end of a needle inserting device (31). Thereafter, if a plunger is rotated, a needle inserting device (31) is rotated together by it.

Thus a "¬" shaped female groove (34) on the outer surface of a needle inserting device (31) rotated by a plunger (41) is rotated together so that projections (13) on the inner circumferential surface of the front end of a barrel (11), which are positioned circumferentially in a "¬" shaped female groove (34), are rotated until the straight line of a "¬" shaped female groove (34), after that, when a plunger (41) is pulled back, projections (13) is moved forward through the straight line of a "¬" shaped female, and simultaneously a needle inserting device (31) with an attached needle (21) is moved back into a barrel (11) and kept inside.

A plunger (41) is moved backwards until a plunger annular prominence (50) reaches a restraining annular prominence (16) of a barrel. And then, a plunger is broken off at a cutting notch (45). Thus the broken plunger (42) is inserted into a barrel from the front end of a barrel. In other words, a rear restraining stop projection (51) of a plunger (41) is inserted until it reaches the inside of a projection (31) located in the inside of a front inserting hole (12) of a barrel (11). A plunger (41) which is locked in an inserting hole (12) is not pulled back easily because a rear restraining stop projections (51) is engaged with a projection (31) in the front end of an inserting hole.

Consequently, a needle inserting device (31) including a needle (21) is throughly inserted into the inside of a barrel (11). A needle stored in the inside of a barrel is safely kept in because an inserting hole (12) is blocked by a broken plunger (41).

## [Effect of device]

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This device can prevent a pricking of doctor, nurse and other medical employee because a needle used for a patient is inserted into the inside of a barrel and kept in.

A syringe having a sharp, needle should be treated with much care, whether it is used or not. Especially, in case of a blood-stained needle used for a patient, it should be treated most carefully.

The diseases such as hepatitis, AIDS and the like can be transmitted through blood.

Therefore, a needle used for such a patient should be handled with utmost care.

This device has an advantage that a needle is safely kept in a barrel because a plunger is broken off after a needle of a syringe is throughly inserted into a barrel. A broken-off plunger is inserted into a barrel through an inserting hole. An inserting hole is blocked with a broken

plunger so that a needle can be kept in and treated safely.

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Thus this is a useful device which makes a used syringe not to be reused and prevents infectious diseases from spreading.

This relates to a device for preventing that disposable syringe is reused and that doctors, nurses, medical employees or others are pricked by the used needle by means of inserting it into a barrel after injection. The needle is attached to the front of a barrel with a needle inserting device, an inserting part is made on male extensions in the front end of the plunger which is inserted into a barrel and a connecting part is made in the back end of a needle inserting device. A male extension of a plunger is assembled with a needle locking device and a needle inserting device which a needle is attached to is inserted into a barrel when a plunger is pulled back. A needle inserting device is kept in the inside of a barrel. Therefore, user doesn't be pricked by the used needle. Consequently, this safety syringe can prevent infectious diseases such as hepatitis and AIDS from spreading.

Some important aspects of the safety syringe according to the second embodiment are as follows:

This safety single use syringe is composed of a barrel (11), a needle (21), a plunger (41) and a needle inserting device (31), same as a general syringe which has a barrel into which the liquid medicine is sucked, a piston and a plunger inside the barrel, and a needle is put on the front tip of the barrel. There is a number of projections (13) in the inside of the front end of an inserting hole (12) of the above barrel (11), the circular stop prominence (15) at the inner surface of a barrel (11), a circular restraining prominence (16) inside the rear end of a barrel, a needle fixing device (32) to insert a needle (21) at the center of a needle inserting

device (31), a number of "¬" shaped grooves (34) with the wide entrances at an outer surface (33) of a cylindrical part of a needle fixing device (32) in order to be assembled with a projection (13) located at an inner surface of an inserting hole (12) of the above cylindrical barrel (11), an 0-ring (35) in the rear of the grooves, a number of the inserting grooves (37), a connecting device (43) of upper and lower part with restraining prominences (43') at the front end of a plunger (41) to be assembled with a piston (42), an empty part (47) at the front end of a plunger (41) to be assembled with a piston (42), a cutting notch (45) at the front part of a plunger (41) in order to be easily broken off, a circular stop prominence (50) at the front part of a plunger (41) reaching to the rear of a piston (42), a rear stop projection (51) at the longitudinal center of a plunger, an empty part longitudinally from a rear stop projection (51) to a cutting notch (45) in the central inside of a plunger.

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A relevant difference between the first and the second embodiment is as follows:

According to the first embodiment, the plunger (41) has a cap (49), which serves to close the front hole of the cylinder (11) after injection, i.e. after retraction of the needle (21) into the cylinder (cp. Fig. 10 and 11).

According to the second embodiment, a part of the plunger (11) itself serves (after breaking the plunger) to close the front hole of the cylinder (11) after injection, i.e. after retraction of the needle (21) into the cylinder. To close the front hole, the part of the plunger is inserted into the cylinder (cp. Fig. 16 and 18). Accordingly, the costs for the manufacturing of the cap (e.g. the cost for providing a mold) are saved.

In the above specification, the terms barrel and cylinder are used as synonyms. The needle inserting device or needle inserter (31) may as well be termed needle holder.

# **ABSTRACT**

The invention provides a safety syringe, which has a cylinder (11), a syringe needle (21), a needle holder (31) associated to the cylinder and adapted to hold the syringe needle, and a plunger (41) associated to the cylinder (11), wherein the plunger (41) comprises a piston (42) and serves to inject a filling of the cylinder (11) via the syringe needle (21), and wherein the plunger (41) can be coupled with the needle holder (31) arranged in the region of a front hole (12) of the cylinder (11), to retract the needle holder (31) together with syringe needle (21) into the cylinder (11) by pulling the plunger (41).